



October 20, 1999

Dockets Management Branch (HVA-305)
Food and Drug Administration
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Rockville, MD 20852

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Re: Docket No. 99D-4201
Guidance for Industry: Dioxin in Anticaking Agents Used in Animal Feed and
Feed Ingredients; Availability

Dear Ms. or Mr.:

Thank you for sending the FDA pre-publication announcement concerning the results of FDA testing of clay-based anti-caking agents for dioxins. Bentonite Performance Minerals is pleased that the FDA sampled our product, **AGRI-FLEX™ Granular** Animal Feed Bentonite, and found no detectable levels of 2,3,7,8 TCDD, 1,2,3,7,8 PeCDD or other dioxin congeners. FDA results support the previous analysis of our product that reported no 2,3,7,8 TCDD at the detection limit of analysis carried out on our product. Our initial analytical results were included in the report submitted to the FDA by the American Feed Industry Association led "Dioxin Task Force."

The proposed guidance for industry groups the anti-caking agents that tested positive to 1,2,3,7,8 PeCDD or 2,3,7,8 TCDD as "*mined clay products*." The information provided in the guidance for industry does not support such a grouping. The guidance for industry reports that materials labeled as "silicate" and "lime" also tested positive to one or more dioxin congeners. Neither of these descriptions can accurately be termed "*mined clay products*".

I am also concerned about the accuracy of the terms "montmorillonite," "bentonite," and "ground clay." Only montmorillonite is a term that has a mineral definition. "Bentonite" is a rock description term and "ground clay" can include ball clay and many other clay minerals. I suggest that the FDA acquire Material Safety Data Sheets for the animal feed anti-caking agents that were collected and tested in late 1998 so that each manufacturer's description of their product can be reviewed.

The animal feed industry and its suppliers do not follow scientific terminology for classification and description of animal feed additives. The Clay Minerals Society is a source of mineral terminology for clay materials and products. The US Geological Survey has the technical capability to determine the mineral and chemical components of the anti-caking additives that the FDA tested for dioxin congeners. I recommend that the FDA ask the U.S. Geological Survey to evaluate the mineralogy of the products that were tested for dioxin congeners and properly name and classify the mineralogical components according to accepted scientific guidelines. The FDA could then make informed and independent decisions concerning the association and occurrence of dioxins with various animal feed additive products.



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The recommendation that companies not use any "*mined clay products*" contaminated with dioxin in animal feed and feed ingredients is premature and incorrect. This ingredient description ignores the "lime" and "silicate" products that tested positive to dioxins, but falls outside accepted descriptions of clay minerals and clay products. A more precise set of definitions is required in order to accurately identify those materials that have tested positive for dioxins.

Sincerely yours,

A handwritten signature in black ink, appearing to read "W. J. Miles". The signature is fluid and cursive, with a large initial "W" and "J" and a stylized "Miles".

William J. Miles, Ph.D.
Director of Technical Services

Cc: S. Gray
M. Steinmeyer



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